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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,281	09/01/2000	John M. Sedivy Ph.D.	3564/1010	5838

29933 7590 07/02/2003  
PALMER & DODGE, LLP  
KATHLEEN M. WILLIAMS  
111 HUNTINGTON AVENUE  
BOSTON, MA 02199

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/654,281	SEDIVY PH.D. ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

All participants (applicant, applicant's representative, PTO personnel):

(1) MISOOK YU, Ph.D. (3) \_\_\_\_\_

(2) Elizabeth Spar. (4) \_\_\_\_\_

Date of Interview: 18 June 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Draft Respnose.

Claim(s) discussed: 33.

Identification of prior art discussed: \_\_\_\_\_


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Regarding NINA sent out on 5-19-2003. Method using different active ingredients is different invention. To paraphrase the original invention is to inhibiting some kinases with an agent (the dependent claims say that the agent is RKIP protein). The amended claim caused NINA is drawn to method using agent modulates activity of RKIP.

**PALMER & DODGE LLP**111 HUNTINGTON AVENUE AT PRUDENTIAL CENTER  
BOSTON, MA 02199-7613**FAX**

sending 5 pages (including cover sheet)

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DATE	June 16, 2003	SENDER ID #	
FROM	Elizabeth Spar	CLIENT #	3564/1010
DIRECT DIAL #			
NAME	COMPANY	PHONE #	FAX #
Examiner Yu	U.S. Patent and Trademark Office	703-308-2454	703-746-7647

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**COMMENTS:**

Examiner Yu:

Attached is a draft response to Office Communication to be discussed in our telephonic interview scheduled for June 18, 2003 at 11:00.

Please contact us with any questions at 617-239-0575.

Very Truly Yours,

Elizabeth Spar  
Reg. No. 45,123

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**\*\*\*DRAFT DO NOT ENTER\*\*\*****Express Mail Label No.:****Date of Deposit:****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Sedivy et al.

Serial No.: 09/654,2815

Filed: September 1, 2000

Entitled: KINASE INHIBITORS AND METHODS  
OF USE IN SCREENING ASSAYS AND  
MODULATION OF CELL  
PROLIFERATION AND GROWTH

Examiner: M. Yu

Art Unit: 1642

Atty. Docket No.: 3564/1010

Assistant Commissioner for Patents  
Washington, D.C. 20231**RESPONSE TO OFFICE COMMUNICATION**

This Amendment is filed in response to the Office Communication, dated May 19, 2003, in the above-identified application.

**REMARKS**

The Examiner has stated that amended claim 33 is "directed to a process of inhibiting a signal transduction kinase by adding an agent that interacts with a second protein (the second protein having an RKIP motif)". The Examiner also states that amended claim 33 is "patentably distinct from the invention originally examined, which was a "method of inhibiting a kinase by adding an agent (such as a polypeptide with an RKIP motif) that inhibits the kinase". The Examiner concludes, "[s]ince the invention claimed is no longer the invention originally elected, the amendment is seen as nonresponsive."

Applicants respectfully disagree.

Serial No.: 09/709,945 \*\*\***DRAFT DO NOT ENTER**\*\*\*

As discussed in the MPEP at § 2111 (page 2100-46-47), "During patent examination, the pending claims must be 'given their *broadest reasonable interpretation consistent with the specification*.' *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)." (emphasis added)

"See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the 'PTO applies to verbiage of the proposed claims the *broadest reasonable meaning of the words* in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.')." (emphasis added).

"The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)."

Claim 33 as filed claims "a method of inhibiting the activity of an RKIP-sensitive kinase, comprising the step of contacting said RKIP-sensitive kinase with an amount of an agent which inhibits the activity of said RKIP-sensitive kinase sufficient to inhibit said activity."

Amended claim 33 claims, "a method of inhibiting the phosphorylation activity of a signal transduction kinase that binds an RKIP family member, comprising the step of contacting said RKIP-sensitive kinase with an amount of an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif, wherein said agent inhibits the activity of said signal transduction kinase that binds an RKIP family member, sufficient to inhibit said activity." (Emphasis added)

Applicants submit that "agent" is defined on p. 15, line 13- page 16, line 2, wherein it is

Serial No.: 09/709,945 \*\*\***DRAFT DO NOT ENTER**\*\*\*  
stated,

"[t]he term "agent" means a composition that has the capacity to modify the bioactivity of a nucleic acid encoding or polypeptide comprising an RKIP motif so as to modulate the activity of a signal transduction pathway that is responsive to an RKIP family protein. An "agent" as used herein may either promote or inhibit the function of the signal transduction pathway, the expression of genes regulated by that pathway, or the ultimate outcome of that pathway's activation (e.g., proliferation, apoptosis, differentiation, etc.). Agents can include any recombinant, modified or natural nucleic acid molecule, library of recombinant, modified or natural nucleic acid molecules, synthetic, modified or natural peptide, library of synthetic, modified or natural peptides; organic or inorganic compound, or library of organic or inorganic compounds (including small molecules) where the agent has the capacity to modify the bioactivity of an RKIP motif-bearing polypeptide." (Emphasis added)

The specification also includes a comprehensive section entitled, "Candidate Agents" at p. 60-66 that teaches candidate agents and properties thereof, useful according to the invention. This section teaches (see p. 62-66) nucleic acids and, in particular, antisense nucleic acids, as agents according to the invention.

Applicants also submit that the specification provides working examples of agents that are not polypeptides with an RKIP motif. In particular, Example 2 teaches inhibition of RKIP activity using antibodies and Example 3 teaches inhibition of RKIP activity using antisense molecules.

*invention  
is not  
inhibi*

Applicants submit that claim 33 as filed, is not limited to a particular subset of agents that are polypeptides with an RKIP motif.

The specification clearly teaches inhibition of the phosphorylation activity of a signal transduction kinase with an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif.

It is stated at p. 58, line 19-p. 59, line 3, "[t]he phosphorylation of kinase targets may be monitored as a more direct assay for RKIP activity. Because RKIP family members inhibit



Serial No.: 09/709,945 \*\*\***DRAFT DO NOT ENTER**\*\*\*

kinase activity, monitoring the activity of these target kinases in the presence or absence of candidate RKIP modulators permits one to determine the effect of a candidate modulator on RKIP activity. A decrease in RKIP target kinase activity is indicative of increased RKIP activity, while an increase in target kinase activity is indicative of decreased RKIP activity."

It is also stated at p. 73, lines 9-12, "an agent that enhances RKIP kinase inhibiting activity may be monitored by monitoring RKIP-sensitive kinase activity in the tissue, while an agent that modulates RKIP expression may be monitored by following that expression."

Applicants submit that in view of all of the above, the "broadest reasonable interpretation, consistent with the specification" of the invention as claimed in claim 33, as originally filed, clearly encompasses agents in addition to polypeptides having an RKIP motif, and in particular, agents that interact with a second protein having an RKIP motif. Applicants submit further that amended claim 33 claims an invention that is not patentably distinct from the invention originally examined. Applicants respectfully submit that Applicant's response to the Office Action dated October 17, 2002 is responsive and respectfully request entry of amended claim 33.

Applicant submits that, in view of the above, the claims are patentable and are in condition for allowance. A notice of allowance to that effect is respectfully requested.

Respectfully submitted,

\_\_\_\_\_  
Date

SPAR  
Elizabeth

\_\_\_\_\_  
Kathleen M. Williams, Ph.D.  
Registration No. 34,380  
Attorney for Applicant(s)  
Palmer & Dodge LLP  
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Telephone: 617-573-0100

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